UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA NEUROSCIENCE, INC., Defendants.	)	No. 20-cv-11548-NMG **Leave to File Granted on April 28, 2023**

UNITED STATES' OPPOSITION TO TEVA'S
MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Teva's Motion for Summary Judgment should be denied because it is wrong on the law and mischaracterizes the facts. The evidence is clear that Teva coordinated and conspired with two foundations, Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"), and two contracted vendors, Advanced Care Scripts ("ACS") and AssistRx, Inc. ("AssistRx"), to illegally funnel co-pay assistance to Medicare patients taking Teva's drug, Copaxone. Teva's conduct turned CDF and TAF into conduits, which Teva knew the Anti-Kickback Statute ("AKS") prohibited and applicable guidance warned against.

Teva knowingly caused the submission of false claims by directing its money to Medicare Copaxone patients. Teva accomplished this by (i) referring Medicare Copaxone patients to ACS and AssistRx; (ii) timing its payments to CDF and TAF with its vendors' "batch" referrals of Copaxone patients to the foundations (manipulating the purportedly "first-come, first-served" process); (iii) soliciting and receiving data regarding the number of Copaxone patients enrolled at CDF and TAF; and (iv) using that data to calculate its payments to CDF and TAF for patient enrollment and re-enrollment. Teva engaged in this scheme—while aware that it was prohibited—to generate Copaxone sales. The United States has identified tens of thousands of kickback-tainted Copaxone Medicare claims. Accordingly, there is overwhelming evidence to support each element of the AKS and False Claims Act ("FCA") violations the government alleges.

Teva's Motion disputes only two of the elements in this case. First, Teva incorrectly argues that the United States must and cannot prove "but-for" causation. Teva's position is inconsistent with First Circuit precedent, and even under such a standard, there is more than sufficient evidence to establish causation. The patients at issue told Teva they needed financial

assistance to afford Copaxone; Teva referred them for financial assistance and directed its funds to those patients; Teva confirmed those patients received the financial assistance; and Teva knew there was a direct connection between its conduct and Copaxone sales for those patients.

Second, Teva incorrectly argues that the government cannot, as a matter of law, prove scienter because its actions were consistent with a *post-hoc*, objectively reasonable interpretation of an ambiguous law. But as a legal matter, there is no such defense in the First Circuit, and even if there were, the AKS is not ambiguous. As a factual matter, Teva has provided no evidence it held a contemporaneous objectively reasonable interpretation of the law, only incomplete, self-serving general averments that the Court should afford no weight. It also has not and cannot identify any applicable ambiguity in the law. There is abundant evidence that Teva acted knowingly and willfully, including that Teva treated its purportedly "charitable" payments as a sales tactic in violation of its own compliance policies. In this Opposition, the government first addresses why, at a minimum, it has raised triable issues on each required element of its claims. Then, the government responds to Teva's meritless arguments.

FACTUAL BACKGROUND

The United States alleges that Teva violated the AKS, 42 U.S.C. § 1320a-7b(b)(2), and caused the submission of false claims to Medicare under the FCA, 31 U.S.C. §§ 3729-3733, by knowingly and willfully paying the out-of-pocket expenses of Medicare patients on Copaxone. ECF No. 1. Teva paid patients' co-pays through two foundations, CDF and TAF, via two contracted vendors, ACS (a specialty pharmacy) and AssistRx. *See* United States' Statement of Facts ("U.S. SOF") ¶ 109. Teva's Motion does not, and indeed cannot, dispute that (i) Teva hired ACS and AssistRx and paid them millions of dollars; (ii) those entities submitted "batch" enrollment files of Teva's Copaxone patients to CDF and TAF following large payments by

Teva; and (iii) Teva provided hundreds of millions of dollars in funding to CDF and TAF. U.S. SOF ¶¶ 109, 112-17, 122. Teva funded CDF and TAF with the intent and understanding that each foundation would use the money to subsidize Medicare patients' Copaxone co-pays, thereby violating the AKS and the FCA. U.S. SOF ¶¶ 118-52. Teva further intended its payments to increase Copaxone sales from these patients, and knew its conduct was illegal. U.S. SOF ¶¶ 118-19, 138-39, 153-208.

Teva effectuated this scheme by referring Medicare-eligible Copaxone patients from its Shared Solutions program to ACS, and later AssistRx, to secure financial assistance for those patients from CDF and TAF. U.S. SOF ¶¶ 112, 117, 121, 123, 132, 136, 208. Teva and ACS coordinated Teva's payments to CDF and TAF (which Teva calculated using the number of Teva's waiting Medicare Copaxone patients) to occur contemporaneously with ACS's referral of those Copaxone patients, and the resulting batch enrollment of those patients at CDF and TAF ensured that Teva's assistance went to Teva's patients. U.S. SOF ¶¶ 122, 124, 128, 178. ACS also regularly reported to Teva the number of Copaxone Medicare patients ACS serviced who were receiving co-pay assistance from CDF and TAF. U.S. SOF ¶ 125-26, 128-29. Teva used that information to confirm the success of its scheme and to budget for future payments to re-enroll those patients with CDF and TAF. U.S. SOF ¶¶ 118, 126, 128-29.

Teva's goal in paying CDF and TAF over $350 million from December 2006 to January 2017 was to make money, as evidenced by, among other things, the return on investment ("ROI") analyses it conducted concerning those payments and its approval of those expenses through its commercial teams rather than its compliance function—in violation of its own charitable donations policies. U.S. SOF ¶¶ 118, 130, 137-38, 182-83. Over the same period of its payments, Teva raised the Copaxone wholesale acquisition cost from approximately $17,000

per year in 2006 to over $85,000 per year in 2017—nearly 20 times the rate of inflation. U.S. SOF ¶ 134. Teva made its payments to CDF and TAF with the intent to induce Medicare-reimbursed Copaxone claims and to ensure that Copaxone patients would never feel the effect of Teva's increasingly exorbitant prices, ultimately yielding Teva substantial revenue from Medicare's Copaxone reimbursements. U.S. SOF ¶ 118-52.

LEGAL BACKGROUND

I. ELEMENTS OF THE AKS AND FCA

To prove a violation of the AKS, the government must show that Teva: (1) paid money (via CDF, TAF, ACS, and AssistRx); (2) to induce patients to use or purchase Copaxone; (3) for which payment may be made, in whole or in part, by Medicare; and (4) the conduct was knowing and willful. *See* 42 U.S.C. § 1320a-7b(b). To prove a violation of the FCA, the government must show that Teva (1) caused the submission of false claims that were (2) materially false, and (3) acted knowingly. *See* 31 U.S.C. § 3729(a)(1)(A). As discussed below, the government has put forward more than sufficient evidence to proceed to trial.

II. HHS-OIG'S 2005 AND 2014 GUIDANCE

As Teva admits it understood, when a pharmaceutical manufacturer pays Medicare patients' co-pays for the manufacturer's own drugs, that conduct implicates the plain language of the AKS. U.S. SOF ¶ 166. In 2005, prior to the beginning of Medicare Part D, the Department of Health and Human Services' Office of Inspector General ("HHS-OIG") published guidance concerning patient assistance foundations, manufacturers' interactions with foundations, and the AKS (the "2005 Guidance"). 70 Fed. Reg. 70623 (Nov. 22, 2005). Teva's employees, including Denise Lynch, were aware of the 2005 Guidance "upon publication." U.S. SOF ¶ 154. The Guidance explained that "donations from a pharmaceutical manufacturer to an independent, *bona*

fide charity . . . should raise few, if any, anti-kickback statute concerns, *so long as*" the manufacturer and the foundations acted in accordance with certain proscriptions. *See* 70 Fed. Reg. at 70626-27 (emphasis added). Those warnings included that, "[n]either the pharmaceutical manufacturer nor any affiliate of the manufacturer . . . exerts any direct or indirect influence or control over the charity or the subsidy program," that "[t]he charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary. . . .," and that "[t]he pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." *Id*. at 70626. The 2005 Guidance further warned that "the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients[.]" *Id*. at 70627. Teva's employees were aware of this specific warning. U.S. SOF ¶¶ 156, 167-68, 201.

In 2014, HHS-OIG issued a Supplemental Special Advisory Bulletin (the "2014 Guidance") reiterating these warnings, and cautioning that advisory opinions issued to foundations:

> [D]o not address actions by donors to correlate their funding of [co-pay foundations] with support for their own products. Such actions may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the [AKS].

79 Fed. Reg. 31120 at 31123 (May 30, 2014) ("2014 Guidance"). Teva was aware of the 2014 Guidance when it came out. U.S. SOF ¶ 158.

III. HHS-OIG'S Advisory Opinions Issued To TAF and CDF

Both CDF and TAF requested and obtained advisory opinions ("AO") from HHS-OIG and shared them with Teva. U.S. SOF ¶¶ 72, 111, 160-62. CDF's AO stated that patient assistance through CDF could "potentially generate prohibited remuneration under the [AKS],"

but that OIG would not impose sanctions provided that a number of conditions were met, including that no data be provided to a contributor "related to the identity, amount, or nature of products or services subsidized" by CDF. U.S. SOF ¶ 161. The AO relied on CDF's representation that its "reports to donors do not contain any information that would enable a donor to correlate the amount or frequency of its donations with the number . . . of patients that use its products." *Id.* The TAF AO contained the same condition. U.S. SOF ¶ 162. Each expressly relied on the requestor's certifications that they would not coordinate referrals with payments or correlate donation amounts with assistance to the donor's patients. U.S. SOF ¶ 163. Moreover, the AOs by their terms and by regulation applied only to the requestor, and "cannot be relied upon by any other individual or entity." U.S. SOF ¶ 164. Teva did not request an AO concerning its conduct. U.S. SOF ¶ 165.

IV. SUMMARY JUDGMENT STANDARD

Summary judgment is only appropriate when the moving party shows that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The Court must deny the motion as long as the non-movant proffers "specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). The non-movant satisfies this standard by identifying "some evidence on which a jury could reasonably find in their favor." *Am. Steel Erectors v. Loc. Union No. 7*, 815 F.3d 43, 71 (1st Cir. 2016) (citation and internal quotation marks omitted). As discussed further below, the government easily meets this standard.

ARGUMENT

I. THE EVIDENCE ESTABLISHES EACH ELEMENT OF THE GOVERNMENT'S AKS-BASED FCA CLAIMS

A. Teva Violated The AKS

1. Remuneration

As this Court has noted, "[r]emuneration is defined broadly . . . and includes payments made both directly and indirectly," and "[s]everal courts have recently have found similar indirect payments to patients through charities to constitute remunerations sufficient to state a claim under the AKS." ECF No. 33 at 9 (citing *United States v. Regeneron*, No. 20-11217-FDS, 2020 WL 7130004, at *29 (D. Mass. Dec. 4, 2020) and *United States ex rel. Strunck v. Mallinckrodt Ard LLC*, Nos. 12-175, 13-1776, 2020 WL 362717, at *13 (E.D. Pa. Jan. 22, 2020) (allegations of remuneration in the form of co-pays via CDF sufficiently pleaded AKS violation)). Teva does not dispute that the payment of patient co-pays constitutes "remuneration" under the AKS, or that CDF and TAF paid Medicare Copaxone patients' co-pay obligations using Teva's funds.

2. Intent To Induce

There is substantial evidence of Teva's intent to induce Copaxone purchases:

- Mr. Hensley testified that Teva structured its payments to CDF and TAF "in a manner that essentially ensured that such donations would benefit only Copaxone patients, and not patients who had been prescribed competitor MS medications." U.S. SOF ¶ 135.
- Teva conducted ROI analyses for its payments to CDF and TAF, evidencing that Teva intended to induce revenue-generating Copaxone purchases. U.S. SOF ¶¶ 118, 130, 137-38, 182-83.
- To calculate the amount of its payments, Teva routinely used data regarding the number of Copaxone patients who were receiving, or awaiting, co-pay coverage from each foundation. U.S. SOF ¶¶ 125-129.
- Once Teva made a payment, it confirmed that the Medicare Copaxone patients it referred to ACS were, in fact, receiving assistance. U.S. SOF ¶ 136.
- Teva's annual budgeting process incorporated the number of Copaxone patients Teva knew to be enrolled at CDF and TAF. U.S. SOF ¶ 129.
- Teva created annual spreadsheets (using actual numbers) that estimated the costs to fund the co-pays of Medicare Copaxone patients it referred to ACS. U.S. SOF ¶ 129.

- Teva coordinated with CDF and TAF to time mid-year batch patient referrals with its payments. U.S. SOF ¶¶ 122, 124, 128, 178.
- Teva excluded Medicare patients from its free-drug program, and structured an alternate "free" Copaxone program for Medicare patients, which was intended to generate revenue by "flipping" patients to co-pay assistance. U.S. SOF ¶¶ 113, 130-31, 137. Teva viewed this as an "investment" towards "gross margin" from those patients after transitioning them to co-pay assistance the following year. U.S. SOF ¶ 130.
- Teva knew that it would lose many Copaxone patients without co-pay assistance. One analysis described Teva's Medicare co-pay assistance program as a "strategy" to maintain compliance and adherence for Copaxone in the face of "strategic initiatives" from competitors to "*steal our Medicare pt base*." U.S. SOF ¶ 138 (emphasis added).
- Teva's Motion does not contest that "at least one purpose" of its contributions was to induce Copaxone sales, and Teva witnesses have admitted as much. U.S. SOF ¶¶ 138-39.

In sum, Teva intended to induce Copaxone fills by implementing a system to ensure that Teva's payments benefited Copaxone patients—and not patients of competing drugs.

3. Knowingly And Willfully

The evidence also shows that Teva acted knowingly and willfully. "Knowing" under the AKS "simply means to do something voluntarily, to do it deliberately, not to do something by mistake or by accident or even negligently." *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989). There is no dispute that Teva acted voluntarily in providing money to CDF and TAF, totaling over $350 million from 2006 to 2017. U.S. SOF ¶ 109. With respect to "willfully," Teva employees knew they were "do[ing] something purposely that [the] law forbids." *Bay State*, 874 F.2d at 33.

First, there is substantial evidence that Teva employees understood the AKS and the Guidance. Teva admits that it knew it could not pay Copaxone Medicare patients' co-pays directly, and that it received the 2005 and 2014 Guidance and the AOs. U.S. SOF ¶¶ 154, 158, 166-68. Teva's "donation agreement" with CDF explicitly referenced the AKS and the

Guidance. U.S. SOF ¶ 110. That agreement, which both Ms. Lynch and Larry Downey, the CEO of Teva Neuroscience, signed in 2006, specifically provided that CDF "shall be [] a *bona fide*, independent charity as described by the [2005 Guidance]." *Id*. In 2010, Michael Banigan, Founder of CDF, sent Ms. Lynch a "legal analysis of the risks associated with a Medicare Only PAP" that was prepared by "the attorney who was instrumental in writing the OIG rules." U.S. SOF ¶ 167. In that analysis, Kevin McAnaney, former Chief of the Industry Guidance Branch of HHS-OIG, warned:

> As a threshold matter, any knowing payments by a pharmaceutical manufacturer or other provider to satisfy a federal health care program enrollee's cost sharing obligations would almost certainly violate the federal anti-kickback statute. In evaluating a pharmaceutical company's donation to a PAP, the critical issue is the nexus between the pharmaceutical company's payment, the Medicare patient, and the pharmaceutical.

Id. In May 2012, a Teva employee circulated, to Jennifer Clark among others, a 2008 PowerPoint presentation from Sidley Austin LLP, on "Legal Considerations in Developing Patient Assistance Programs." The presentation summarized the AKS and noted that, according to HHS-OIG, "PAPs present 'all of the usual risks of fraud and abuse associated with kickbacks.'" U.S. SOF ¶ 168. The presentation reiterated HHS-OIG's warning that "the independent charity PAP must not function as a conduit[.]" U.S. SOF ¶ 168. Teva knew that its "donations made to patient assistance programs cannot be and should not be tied directly to utilization of COPAXONE[.]" U.S. SOF ¶ 169.

Second, Teva's very effort to devise its schemes with ACS (and later AssistRx), CDF, and TAF shows that it knew the legal prohibitions and willfully sought to circumvent them. Teva, of course, could have made donations to patient assistance foundations with no coordination or analysis. Prior to engaging in the conduct at issue, Teva made payments to two other foundations—Patient Services, Inc. ("PSI") and the National Organization of Rare

Diseases ("NORD"). U.S. SOF ¶ 170. Teva became dissatisfied with both organizations when each did not direct Teva's funding to Copaxone patients as Teva wanted. U.S. SOF ¶ 171. For example, prior to the enactment of Medicare Part D, Ms. Lynch stopped authorizing payments to PSI, complaining to Mr. Hensley that PSI had "burned" her by using a prior payment to cover non-Copaxone patients' co-pays. U.S. SOF ¶ 171. Ms. Lynch said that she was "tired" of other pharmaceutical manufacturers "riding on [Teva's] coattails." U.S. SOF ¶ 171. Similarly, Teva stopped contributing to NORD because Teva was the only contributor to NORD's MS fund and NORD would not commit to prioritizing Copaxone Medicare patients "up at the front of the line for processing." U.S. SOF ¶ 171.

Searching for a "Medicare Part D Conversion Program," Teva partnered with ACS and CDF (and later TAF, and later still, AssistRx) to do what PSI and NORD would not: direct Teva's funds specifically to Copaxone patients. U.S. SOF ¶¶ 132, 173. Teva entered into a contract with ACS in October 2006, and a "Donation Agreement" with CDF in December 2006. U.S. SOF ¶ 172. CDF and ACS expressly discussed directing Teva's funding specifically to Copaxone patients. U.S. SOF ¶ 173. Mr. Hensley, who co-founded ACS, understood that the "intent" of Teva's arrangement with ACS and CDF was to direct *Teva's funds* to Medicare beneficiaries on *Teva's drug*, Copaxone. U.S. SOF ¶ 176. ACS touted the success of its "conversion" of Medicare Copaxone patients into CDF. U.S. SOF ¶ 132. Later, Teva entered into similar agreements with TAF and AssistRx, each of which Mr. Hensley also co-founded. U.S. SOF ¶ 175; *see also* ¶ 97. Coordinating heavily with Mr. Hensley and ACS from the start, Teva turned TAF's MS fund into a direct conduit for Copaxone Medicare patients. U.S. SOF ¶ 176-79. In 2010, Teva made nearly 99 percent of all payments to TAF's MS fund, and over 95 percent of the fund's payments went to Copaxone patients. U.S. SOF ¶ 179. That coordination

continued even after Mr. Hensley resigned from TAF's board due to scrutiny over conflicts of interest—in his resignation email to TAF's executive director, Mr. Hensley stated: "Of course, I will remain on [sic] constant contact with Teva and make sure that relationship does not go away at all." U.S. SOF ¶ 180. The relationships were mutually lucrative: Teva was a major source of revenue for ACS and AssistRx (each of which received fees for enrollments), a major source of pharmacy referrals for ACS (which dispensed an outsized share of Copaxone for Medicare patients as a result of Teva's referrals), and also a significant source of funds to TAF and CDF via administrative fees. U.S. SOF ¶¶ 194-95. Mr. Hensley personally made about $48 million when he sold ACS in 2009 and is an owner of AssistRx, which received fees from TAF and still has substantial annual revenues from Teva. U.S. SOF ¶ 197. For his part, Mr. Banigan personally reaped more than $30 million after he sold software, DiseaseTrak, to CDF, for more than $60 million. U.S. SOF ¶ 196. Teva's conduct generated over one billion dollars in Copaxone sales for Medicare patients. U.S. SOF ¶¶ 140-141.

Third, Teva did not follow its own charitable donations policies. Notwithstanding its "integrity principles," which required any charitable contributions to undergo review by Teva's compliance department, Teva's sales and marketing departments determined Teva's purportedly "charitable" contributions. U.S. SOF ¶¶ 184-88. That is, Teva ignored its own "integrity" and compliance policies to allow the Copaxone commercial team to direct hundreds of millions of dollars to CDF and TAF to generate Copaxone sales. U.S. SOF ¶¶ 184-88.

Fourth, Teva concealed its contributions to CDF and TAF from the public and its competitors. U.S. SOF ¶¶ 189-90. Teva did so because its intent was not charitable, but rather to generate Copaxone sales. U.S. SOF ¶¶ 135, 171, 188-90.

B. Teva Violated the FCA

1. Falsity And Materiality

The United States will show at trial that Teva violated the AKS, thereby establishing falsity for purposes of the FCA. As discussed in its affirmative motion for partial summary judgment, (ECF Nos. 160, 161), incorporated here by reference, the Court should enter summary judgment in the government's favor on the element of materiality as a matter of law. ECF No. 161 at 3. Additionally, there is substantial evidence that the government will not pay for "services or products if they were delivered in a manner that does not comply with the AKS." U.S. SOF ¶¶ 209-10. As a legal and factual matter, then, AKS compliance is material to payment, and claims resulting from an AKS violation are *per se* materially false.

2. Causation

The government incorporates its previous arguments concerning the evidence of causation. ECF No. 161 at 5. Under the First Circuit's decision in *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019), which embraced the Third Circuit's decision in *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96-98 (3d Cir. 2018), the government need not establish "but for" causation to prevail at trial. The government need only show a "causal connection" between Teva's contributions to CDF and TAF and the resulting co-pay-assisted Copaxone claims that Medicare reimbursed. *Guilfoile*, 913 F.3d at 190. Regardless, there are at least four categories of evidence establishing causation, any one of which would be sufficient to defeat summary judgment.

First, all of the evidence regarding Teva's intent to induce Copaxone prescription fills (as summarized above in Argument Section I.A.2) also serves as evidence of causation, since it establishes Teva's own understanding—as the party identifying patients in need, referring those patients for assistance, funding those patients, and receiving revenue from prescription fills—that

its payments caused Copaxone fills.

Second, the Medicare Copaxone patients at issue *told Teva they needed financial assistance to afford Copaxone*. U.S. SOF ¶¶ 142. Teva, ACS, AssistRx, CDF, and TAF all confirmed the financial need of patients, as the foundations limited assistance to patients with income of 5 or 7 times the federal poverty limit, which the vast majority of Medicare patients met. U.S. SOF ¶ 146.

Third, Teva documents and witness testimony regarding the effects of Teva's payments show a causal connection, including that Teva would have lost sales from Medicare Copaxone patients if it did not provide co-pay assistance. U.S. SOF ¶¶ 138, 142-43, 183. In advocating for budget approvals, Teva employees knew "[n]ot funding these patients has a direct and immediate impact on [Copaxone] units." U.S. SOF ¶¶ 138, 183.

Fourth, expert reports and testimony confirm the causal link between Teva's payments and Medicare Copaxone claims caused by Teva's conduct. Dr. Jacob Rube opined that out-of-pocket cost is central to medication selection and that patients often select different medication, switch drugs, or discontinue treatment due to cost. U.S. SOF ¶¶ 144-45. Economist Leemore Dafny, Ph.D., opined that making drugs less expensive for patients through co-pay subsidies makes it more likely that patients will purchase them. U.S. SOF ¶ 150. Economist Philip Ellis, Ph.D., found strong positive statistical correlations between Teva's payments to CDF and TAF and those funds' enrollments of and disbursements for Copaxone patients. U.S. SOF ¶ 147. Data analysis expert Ian Dew matched Medicare Copaxone claims for which CDF and TAF paid some or all of the beneficiary's co-pay for Copaxone. U.S. SOF ¶¶ 140-41. Mr. Dew further identified matched Medicare claims for Copaxone patients who were: 1) referred by Teva to ACS—*i.e.*, patients who told Teva they needed financial assistance to afford Copaxone; and 2)

enrolled for assistance at CDF or TAF following a Teva payment to the respective foundation. U.S. SOF ¶ 141.

Finally, Teva concedes that its payments caused Copaxone patients to fill their medication. In attempting to convince the Court of its beneficence, Teva acknowledges that "financially needy Medicare patients would need to seek out alternative sources of funding" for their Copaxone—because they could not have afforded it. ECF No. 163 at 2. Conversely, Teva's experts' arguments concerning the potential availability of alternative funding are speculative and unsupported by any evidence. U.S. SOF ¶ 151.

3. Knowingly

As discussed above, the evidence shows that Teva knew that it could not direct its payments to its own patients, but did so anyways in order to generate Medicare Copaxone sales, which is enough to establish scienter on the AKS violations. Because "[t]he AKS's scienter element is harder to meet than the FCA's scienter standard," satisfying the AKS's scienter standard satisfies the FCA's scienter standard. *United States ex rel. Gohil v. Sanofi U.S. Servs., Inc.*, No. 02-2964, 2020 WL 4260797, at *13 (E.D. Pa. Jul. 24, 2020); *see also United States v. Mallory*, 988 F.3d 730, 737 (4th Cir. 2021)).

II. TEVA'S ARGUMENTS ARE UNAVAILING

Teva's Motion is premised on incorrect legal theories and an incorrect view of the facts. First, Teva is wrong that "but for" causation is required—and wrong that the United States cannot show but-for causation if needed. Second, Teva is wrong regarding its scienter—Teva's cited testimony fails to establish that Teva's conduct was "objectively reasonable." Teva both misstates the applicable guidance documents and mischaracterizes the evidence, which demonstrates that Teva's profit-driven conduct was designed to violate the AKS.

A. The Government Is Not Required To Prove But-For Causation

The government is not required to show but-for causation in AKS-FCA cases. This Court already expressly rejected the actual inducement argument that Teva now attempts to relitigate. ECF No. 64 at 7 ("The relevant question is not whether a particular patient was in fact induced to purchase Copaxone but rather whether Teva intended to induce patients to purchase Copaxone by Teva's donations."); ECF No. 33 at 19 ("Teva's assertion that the government cannot link its donations to specific false claims . . . is unpersuasive."); *see also Regeneron*, 2020 WL 7130004, at *11 (quoting *Greenfield*, 880 F.3d at 96, and collecting cases); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601, 2018 WL 1996829, at *6 (D. Mass. Apr. 27, 2018); ECF No. 161 at 5-10 (U.S. Mot. For Partial Summ. J.).

1. *Cairns* And *Hathaway* Are Not The Law Of This Circuit And Are Unhelpful To Teva In Any Event

Teva's reliance on *United States ex rel. Cairns v. D.S. Medical, Inc*., 42 F.4th 828 (8th Cir. 2022) and *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023) is misplaced. *See* U.S. Mot. for Partial Summ. J., ECF No. 161 at 7-8. To summarize: *first*, *Cairns* and *Hathaway* are contrary to the law of this Circuit. *Compare Guilfoile*, 913 F.3d at 190 (binding First Circuit precedent expressly embracing *Greenfield*'s approach to causation, which "requir[es] something less than proof that the underlying medical care would not have been provided **but for** a kickback," *Greenfield*, 880 F.3d at 96 (emphasis added)), *with Cairns*, 42 F.4th at 836, and *Hathaway*, 63 F.4th at 1054 (each expressly deviating from *Greenfield*'s approach to causation). Teva's assertion that the "but-for" causation standard articulated in *Cairns* and *Hathaway* is "consistent" with *Guilfoile* is incorrect. *Second*, the Eighth Circuit explicitly acknowledged the narrow scope of its holding, including limiting it to cases in which "a plaintiff seeks to establish falsity or fraud through the 2010 amendment." *Cairns*, 42 F.4th at

836-37 ("We do not suggest that every case arising under the False Claims Act requires a showing of but-for causation[.]"); *see also United States ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, No. 13-CV-3003, 2023 WL 36174, at *2 (D. Minn. Jan. 4, 2023). Under *Cairns*, "if Plaintiffs can establish all the elements of their material falsity theory without reliance on the 2010 Amendment—including that the purported AKS violations were material— Plaintiffs need not prove but-for causation to establish liability under the FCA." *Fesenmaier*, 2023 WL 36174, at *3; *see also Bawduniak*, 2018 WL 1996829 at *5 (an FCA plaintiff need only show that the "United States cannot pay a claim *induced* through the payment of a kickback") (emphasis added).

The government can establish material falsity without relying on the 2010 Amendment, by showing that compliance with the AKS is a material precondition of payment. *See, e.g., United States ex rel. Hutcheson v. Blackstone Medical, Inc*., 647 F.3d 377, 392-94 (1st Cir. 2011) ("If kickbacks affected the transaction underlying a claim, as Hutcheson alleges, the claim failed to meet a condition of payment."). In *Hutcheson*, the First Circuit expressly rejected the argument that otherwise medically necessary AKS-tainted claims are not materially false, stating that "an implicit medical necessity requirement impermissibly cabins what the government may consider material." *Id.* at 395. Simply put, CMS does not pay for products or services that are tainted by kickbacks. As the relevant government witness has attested, "compliance with the AKS is material to CMS's payment decision." U.S. SOF ¶¶ 209-10.

2. Even If The Government Were Required To Establish "But For" Causation, The Court Should Still Deny Teva's Motion

As discussed above in Argument Section I.B.2, even if the United States did have to show but-for causation (which is not the law), there is ample evidence establishing causation.

B. Teva Is Not Entitled To Summary Judgment on Scienter

As a threshold matter, the Court should reject Teva's arguments concerning scienter because the United States has presented sufficient evidence for a jury to find that Teva acted with the requisite scienter. *See* Argument, §§ I.A.2-3; I.B.3. Intent is a highly fact-intensive inquiry which "requires an evaluation of the weight and credibility of the testimony and evidence . . . that is uniquely within the province of the trier of fact[.]" *Woods Hole Oceanographic Inst. V. ATS Specialized, Inc.*, 557 F. Supp. 3d 261, 283 (D. Mass. 2021) (Gorton, J.) (citation omitted). The AKS does not require proof of specific intent. 42 U.S.C. § 1320a-7b(h). Furthermore, intent "may be proven (and usually is) by indirect and circumstantial evidence." *United States v. Sawyer*, 85 F.3d 713, 733 (1st Cir. 1996) (citing, *inter alia*, *United States v. O'Brien*, 14 F.3d 703, 706-707 (1st Cir. 1994) ("As a general matter, the prosecution's burden of proof can be satisfied by either direct or circumstantial evidence, or by any combination thereof.")). Teva's scienter evidence consists of selective, self-serving statements by its employees and co-conspirators that are subject to inherent credibility considerations; the Court should "set … aside" this evidence at the summary judgment stage. *See Manganella v. Evanston Ins. Co.*, 702 F.3d 68, 74-75 (1st Cir. 2012) (citing *Blanchard v. Peerless Ins. Co.*, 958 F.2d 483, 490-91 (1st Cir. 1992)). In any event, much of Teva's cited witness testimony *supports* a finding that Teva acted with scienter. In addition, Teva's "objectively reasonable interpretation" defense is neither cognizable, reasonable, nor supported by the evidence.

1. The Court Should Disregard Teva's Cited Testimony At Summary Judgment; It Is Also Misleading And Incomplete

The testimony Teva cites should be disregarded at summary judgment because it carries with it inherent credibility concerns. Every witness whose testimony Teva cited was a Teva employee or an alleged co-conspirator; as such, "even if the [testimony] were relevant here, [the

Court should] set it aside for the purposes of resolving [the] motion because a reasonable factfinder could refuse to credit it." *Manganella*, 702 F.3d at 75. The personal and professional implications to witnesses who admit to participating in AKS violations are obvious. Mr. Hensley and Mr. Banigan, each of whose testimony Teva cites in its Motion, made tens of millions of dollars from related for-profit businesses they owned. U.S. SOF ¶¶ 196-97. And, in fact, the same witnesses Teva cites also provided testimony about the details of the scheme that undercuts Teva's claimed lack of scienter. *See, e.g.,* U.S. SOF ¶¶ 118, 131, 136, 139, 173, 176, 181-82, 199.

There is ample evidence that Teva acted knowingly and willfully, including testimony from Teva witnesses that they understood it would be wrong for Teva to direct its payments specifically to Copaxone patients rather than all MS patients generally. U.S. SOF ¶¶ 200-01. Yet, the evidence is clear that these same employees engaged in schemes to direct Teva's payments specifically to Copaxone patients. *See, e.g,* U.S. SOF ¶¶ 122, 124, 127, 130, 131, 135, 171, 173, 174, 178. That Teva employees engaged in conduct they knew was prohibited is powerful evidence that Teva acted willfully.

Furthermore, Teva predicates its assertions that its personnel did not act willfully on inadmissible legal advice. *See* ECF No. 163 at 9 (noting that "Teva's Legal department was 'really involved'"); 10 (noting that "Ms. Lynch consulted with people in Teva's legal . . . department"); 23-24 ("Relevant Teva personnel routinely sought advice from attorneys so as not to violate the law."). The Court should disregard Teva's invocations of legal advice because, after *months* of delays necessitating a Court-mandated deadline, Teva stated it was not going to invoke an advice of counsel defense and refused to permit discovery concerning *any aspect* of legal advice. *See* ECF Nos. 92-6, 133, 147.

2. Objective Reasonableness Is Not The Law, And Teva Did Not Follow An Objectively Reasonable Interpretation Of The Law

As a threshold matter, the Court should decline to follow *United States ex rel. Schutte v. Supervalu, Inc.*, 9 F.4th 455 (7th Cir. 2022), for which the Supreme Court heard oral argument on April 18, 2023. 143 S. Ct. 644 (2023).[1] *Supervalu* looked to the Supreme Court's holding in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007)—which interpreted the scienter standard under the Fair Credit Reporting Act—in concluding that a defendant can escape FCA liability if it can advance an objectively reasonable interpretation of an ambiguous regulation to justify its conduct, even if that explanation comes after-the-fact. *Supervalu*, 9 F.4th at 470. This standard turns FCA scienter on its head. *Id.* at 476 (Hamilton, J., dissenting). The Supreme Court subsequently has made clear that *Safeco*'s scienter holding—and in particular the footnote concerning subjective bad faith upon which *Supervalu* relies—is context-dependent and does not broadly apply to all statutes. *See Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 105 n.* (2016).

The jury should be permitted to consider the mass of contemporaneous evidence showing that Teva knew it was acting unlawfully. *See, e.g.*, *Halo*, 579 U.S. at 105 ("[C]ulpability is generally measured against the knowledge of the actor at the time of the challenged conduct."); *Mallory*, 988 F.3d at 736-38 (upholding jury verdict against defendants in an AKS-based FCA case based on circumstantial evidence of willfulness notwithstanding defendants' argument that the AKS was ambiguous); *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017) ("The . . . conclusion that a finding of scienter can be precluded by a defendant's identification of a reasonable interpretation of an ambiguous regulation that would

[1] The government recently addressed the inapplicability of *Supervalu* in this context in *United States v. Regeneron*, No. 20-cv-11217-FDS (D. Mass. 2020), ECF No. 274 at 27-31.

have permitted its conduct is erroneous.").

a. Teva Has Not Put Forth Evidence It Interpreted The AKS Or HHS Guidance In A Manner That Blessed Its Conduct

As the Court has held in this case, Teva has not identified any interpretation of the AKS or guidance documents in this case:

> Teva has failed to provide an adequate foundation for its good faith defense in this case. In response to [] interrogatories asking it to state the basis for its good faith defense, Teva did not identify the nature of its interpretation of the SABs or provide any evidence that it held any contemporaneous interpretation of the SABs. Rather, it cited to the SABs themselves and its contracts with CDF, TAF, ACS, and AssistRx, without identifying any portions thereof upon which it relied.

ECF No. 143 at 7; U.S. SOF ¶ 198. Teva witnesses have not testified to interpreting the AKS, 2005 Guidance, or 2014 Guidance. To the contrary, they have testified they did *not* have any such interpretations. U.S. SOF ¶ 199. Patricia Glover, Teva's former Chief Compliance Officer, testified that she was *not* involved in Teva's arrangements and that she *would* have been concerned about Teva efforts to direct its payments to its own patients. U.S. SOF ¶ 200.

b. Neither The AKS Nor The 2005 Guidance Are Ambiguous

Even if the Supreme Court were to affirm *Supervalu*, Teva has not and cannot point to any ambiguity in the AKS. Despite claiming that "The AKS . . . [is] Ambiguous," ECF No. 163 at 20, Teva fails to identify a single ambiguous phrase in the text of the AKS. *See Pfizer v. Dep't of Health & Human Srvs.*, 42 F.4th 67, 74-77 and n. 6, 10 (2d Cir. 2022) (rejecting arguments concerning AKS's ambiguity). As the Supreme Court and many other courts have held, broad prohibitions are not the same as ambiguous prohibitions. *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980); *United States ex rel. Streck v. Takeda Pharms. Am., Inc*., No. 14-cv-9412, 2022 WL 595308, at *12 (N.D. Ill. Feb. 28, 2022) ("Courts have recognized that '[b]y requiring regulations to be too specific [courts] would be opening up large loopholes allowing conduct

which should be regulated to escape regulation.'") (internal citation omitted). Teva's failure to point to any ambiguity in the text of an applicable statute or regulation is fatal to Teva's alleged defense. *Supervalu*, 9 F.4th at 468 ("The objectively reasonable inquiry hinges on the text of the statute or regulation that the defendant allegedly violated and as such is a question of law" (citing *Safeco*, 551 U.S. at 69)).

Instead of pointing to an ambiguity in the text of a statute or regulation as required, Teva argues that the *2005 Guidance* (not the AKS) is ambiguous. The Guidance is neither a statute nor a regulation; therefore, it offers Teva no defense under *Safeco*. *Safeco* aside, Teva makes no argument that Teva employees interpreted the Guidance in a way that supported its conduct—nor can it, since Teva cannot identify any evidence whatsoever that it held or relied on any contemporaneous interpretation of the Guidance. This is consistent with Magistrate Judge Boal's finding that "Teva did not identify the nature of its interpretation of the SABs or provide any evidence that it held any contemporaneous interpretation of the SABs." ECF No. 143 at 7. This Court recently affirmed Judge Boal's Order. ECF No. 168. Accordingly, Teva has no argument that its "interpretation" negates any potential finding on willfulness. *See, e.g.*, *United States ex rel. Hueseman v. Pro. Compounding Centers of Am., Inc.*, No. SA-14-CV-00212, 2023 WL 2669879, at *13 n. 7 (W.D. Tex. Mar. 27, 2023) (rejecting *Safeco* argument because defendant's purported interpretation was unreasonable); *Waldmann v. Fulp*, 259 F. Supp. 3d 579, 629 (S.D. Tex. 2016) ("[A] defendant [cannot] disregard its obligations under the FCA and then argue *ex post facto* that a reasonable interpretation of applicable law supports its prior position."). Nor does the evidence support a potential defense to willfulness based on such an "interpretation." The most that Teva offers is self-serving denials from its witnesses that they acted willfully. *See Blanchard*, 958 F.2d at 490-91; *Manganella*, 702 F.3d at 74-75.

Moreover, even if Teva's mere assertions that the 2005 Guidance is ambiguous sufficed to state a defense, the text of the Guidance is not ambiguous. *First*, Teva argues that the Guidance documents are ambiguous because they "allow for single-drug funds." Mem. at 20. The Guidance is not ambiguous on this issue. Teva misleadingly cites to a footnote from the 2005 Guidance, which actually states that OIG would *not* consider such funds, if "formed, funded or controlled" by a manufacturer, to be independent. SOF ¶ 157. It is similarly untrue, as Teva suggests, that the 2014 Guidance "allows the same." Mem. at 20 (citing 70 Fed. Reg. 31120, 31122). To the contrary, the 2014 Guidance warned that single-drug funds "*will be subject to scrutiny*" and that AKS violations can be determined "only on a case-by-case basis after examining the applicable facts and circumstances, *including the intent of the parties*." U.S. SOF ¶ 159 (emphasis added). Accordingly, Teva's assertion that the Guidance is ambiguous as to what "intent would violate the AKS" is baseless. Mem. at 21. Teva's claim that Heather Westphal, HHS-OIG counsel, made the "startling admission that intent to support patients on one's own product is ***not*** necessarily violative of the AKS," is no evidence of ambiguity and should have come as no surprise to Teva. Mem. at 20-21; U.S. SOF ¶ 206. It is black letter law that intent to induce is not enough to prove an AKS violation—the government must prove willfulness. 42 U.S.C. § 1320a-7b(b)(2).

Second, Teva argues that the Guidance is ambiguous because it did not explicitly address the solicitation or receipt of product-specific data from a foundation *via a third party*. Mem. at 21. Teva's suggestion that the 2005 Guidance therefore blessed its conduct is baseless. The 2005 Guidance warned all manufacturers, including Teva, against (i) soliciting or receiving Copaxone-specific data from the foundations, (ii) exerting direct or indirect influence or control over a foundation (including via any agent), and (iii) treating a foundation as conduit to direct its

money to its patients. U.S. SOF ¶¶ 155-57. But, Teva did all of these things. *See, e.g.,* U.S. SOF ¶¶ 118-39. Further, there is evidence in the record that Teva knew that the information it received from ACS came straight from CDF or TAF. U.S. SOF ¶ 127. For example, on August 30, 2011, Barb Ross (Teva) emailed Jennifer Clark (Teva) with a subject line "Medicare Patients," and stated that "David [Blanc of ACS] and Zach will be getting numbers first thing in the morning, *they are checking with CDF* for total numbers." U.S. SOF ¶ 125 (emphasis added). Indeed, at certain points, the veil dropped, revealing Teva itself dealt *directly* with the foundations. U.S. SOF ¶ 127 (Mr. Hensley: "I am having a discussion with Denise Lynch at 12:30. She is looking for the total number of Copaxone patients that she needs to fund for next year. Could you provide me with an updated number. I believe the last number we gave them was approximately 3900?"). In any event, while the 2005 Guidance did not expressly use the terms "third-party hubs" or "specialty pharmacies," it plainly cautioned Teva against doing what it did. Teva identifies no reading of the Guidance that blesses its use of ACS and AssistRx to do what it knew it could not do directly.

Third, Teva argues that because the foundations held ultimate control of fund distributions, Teva reasonably could have believed it was acting lawfully. Mem. at 21-22. The Court already has rejected this argument. ECF No. 33 at 12. Nor does Teva advance evidence that it contemporaneously held this position; instead, the evidence shows Teva exerted control to direct its funds to its patients. U.S. SOF ¶¶ 122, 132 173-74, 176-80, 194-99. In any event, the Guidance *also* warns, for example, Teva (i) not to solicit or receive Copaxone-specific data, (ii) not to exert direct or indirect influence or control, and (iii) not to treat the foundations as conduits. U.S. SOF ¶¶ 155-58.

Finally, Teva argues that the existence of the 2014 Guidance proves the ambiguity of the

2005 Guidance. Mem. at 22. It does no such thing. The 2014 Guidance was a "*Supplemental* Special Advisory Bulletin" that updated the 2005 Guidance. Teva does not, and cannot, point to conduct that the 2005 Guidance blessed, but that the 2014 Guidance warned against. Teva advances a *post hoc* claim that the 2014 Guidance "focused" on the donors' conduct, not just the foundations' conduct, Mem. at 22, but the 2005 Guidance *does address* manufacturer conduct, including the use of foundations as conduits and stating, for example, "the *pharmaceutical manufacturer* [should] not solicit or receive data from the charity," and "neither the *pharmaceutical manufacturer* nor any affiliate of the *manufacturer* . . . [should] exert[] any direct or indirect influence or control over the charity." U.S. SOF ¶¶ 155-57.

c. Teva Was Warned

The 2005 Guidance and the 2014 Guidance both warned Teva (and the foundations) against doing what it did. Teva was aware of those documents, which informed Teva that it should not (i) solicit or receive product specific information from the foundations, (ii) exert direct or indirect influence or control over the foundations, or (iii) use the foundations as conduits to direct its payments to Copaxone patients. U.S. SOF ¶¶ 154-59. As detailed herein and in the U.S. SOF, the government has put forward sufficient evidence that a triable issue exists on whether Teva engaged in each of those means of misconduct. Whether Teva stopped doing so after OIG's issuance of the 2014 Guidance proves nothing about Teva's willfulness prior to May 2014, and the evidence shows Teva violated the law post-May 2014. U.S. SOF ¶¶ 115-17, 123, 208. In summary, both the 2005 and 2014 Guidance warned Teva against doing what it did.

Teva nevertheless argues that it was not warned away from its interpretation of the legality of its actions. But, Teva *did not have any* contemporaneous interpretation from which to

be warned away. ECF No. 143 at 7. All Teva offers is its counsel's representation that with respect to Teva's conduct, the "**only** court opinion undersigned counsel is aware of during the relevant time period" was *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1057 (C.D. Cal. 2016). Mem. at 23 (emphasis in original). There is no indication that anyone at Teva considered, or even was aware of, *Celgene*. Further, the court did not issue the *Celgene* opinion until December 28, 2016—it has no possible relevance to almost the entire period at issue in this case. Even if it did, the government has identified evidence that CDF and TAF did not act independently with respect to Teva. Mr. Hensley's affidavit, for example, states that he "understood that Teva's conduct in alerting ACS of a forthcoming Teva donation to CDF or TAF was contrary to the spirit of the OIG guidance and, *in substance*, *caused CDF and/or TAF not to be truly 'independent' of Teva but rather to be mere 'pass-through' vehicles*." U.S. SOF ¶ 207 (emphasis added).

C. Statute of Repose

Finally, Teva contends that the FCA's ten-year statute of repose bars any government claims before April 13, 2008. The parties' tolling agreement took effect on April 24, 2018, and it tolled the time through November 12, 2020. As the government filed its Complaint on August 18, 2020, the government may recover on any FCA claims on or after April 24, 2008.

CONCLUSION

For the foregoing reasons, the United States respectfully requests that the Court deny Teva's motion for summary judgment.

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Respectfully submitted,

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